

## REMARKS

### Introductory Comments

Reconsideration of the above-identified application in view of the above amendments and arguments set forth is respectfully requested.

Claims 1-2, 4-17 and 26 are pending and under consideration.

### Rejection of Claims 1-17 and 26 Under 35 U.S.C. § 112, First Paragraph

Claims 1, 2, 4-17 and 26 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse the rejection.

Specifically, the Examiner states that the specification fails to disclose the “unconjugated” large polycation as recited in the claims. Thus, the Examiner maintains the rejection made in the previous Office Action.

As discussed in Applicants previous Amendments, the specification simply does not teach or disclose that the polycations being added to the assay samples are in a conjugated form or joined to another molecule. In fact, Applicants submit that it is inherent based on the description contained on pages 2-4, 6 and Examples 2-4 of the specification, that the polycations added to the specific binding assays in the claim methods are unconjugated. For example, the specification on page 6, lines 11-22 describes in detail the amount and types of polycations that can be used in the claimed methods. No mention of conjugation to other molecules is made or described. In Example 2, lines 14-17, the specification states “[I]n separate experiments, a polycation, i.e., polylysine, polybrene or MERQUAT, then was added to the TSH Assay Diluent and combined with the serum or plasma sample (150  $\mu$ L) and anti- $\beta$  TSH antibody

coated paramagnetic microparticles (50  $\mu$ L at 0.1% solids) in the first step of the TSH assay” (emphasis added). In Example 3, lines 26-28 the specification states, “[I]n these experiments, a polycation, in particular, a poly-amino acid, was substituted in place of dextran sulfate in the microparticle diluent. The assay then was performed as described in the general procedure above.”

There is nothing in Examples 2 and 3 to suggest that the polycations added to assay samples are conjugated. Certainly if these polycations were conjugated to one or more other molecules, these molecules would be identified as being included in the immunoassay. Their function in the immunoassay would also be identified. As can be appreciated by the Examiner, any molecules added or used to an immunoassay should have a specific purpose. Unnecessary molecules simply are not added.

Furthermore, Example 4, page 12, line 16 – page 13, line 3 states:

“The general procedure of the ARCHITECT total PSA assay is essentially as described for the free PSA assay in Example 3, with the exception that the paramagnetic microparticles are coated with a monoclonal antibody that binds to both free and complexed PSA. Experiments were performed in which unspun samples were subjected to a total PSA assay that utilized a microparticle diluent containing dextran sulfate (at a concentration of 0.05%) or a poly-L-lysine of average molecular weight 5200 or 11,200 (in place of dextran sulfate) at a concentration of 0.005%. The results, shown in Table 3, demonstrate that poly-L-lysines of different average molecular weights are effective at decreasing interferences in total PSA measurements in unspun samples without interfering with or altering the high functional sensitivity of the total PSA assay” (emphasis added).

The above quoted portion of Example 4 in which the effectiveness of different molecular weights of poly-L-lysine are compared to one another further supports Applicants argument that the polycations are unconjugated.

Applicants submit that it would be clear to one skilled in the art that after reading Applicants specification that Applicants claimed method inherently

discloses the addition of unconjugated polycations to specific binding assays for the purpose of decreasing interferences. As discussed in the Manual of Patent Examining Procedure in Section 2163.07(a) (8<sup>th</sup> Edition, Rev. 2, May 2004), when a patent application discloses that a device inherently performs a function or has a certain property or operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it (emphasis added). Therefore, based on the portions of the specification discussed above, Applicants have inherently disclosed that the polycations used in the claimed methods are unconjugated. Therefore, Applicants submit that the specification reasonably conveys to those skilled in the art that at the time this application was filed that Applicants were in possession of the claimed invention.

Thereupon, for the above reasons, Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4-17 and 26 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicants thank the Examiner for withdrawing the rejection of claims 1 and 7 under 35 U.S.C. § 102(b) as being anticipated by Siedel *et al.*, U.S. Patent Number 5,288,606, in the previous Office Action.

Applicants also thank the Examiner for acknowledging that claims 1, 2, 4-17 and 26 are allowed over the prior art.

## CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Section 112. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

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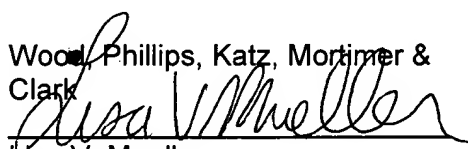
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Respectfully submitted,  
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